

Applicants : JIN, et al.
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In response Applicants respectfully traverse this ground of rejection. Claim 1 recites "A stable aqueous/aqueous emulsion system prepared with appropriate hydrophilic polymers." Applicants maintain that the claim is clear to an ordinary skilled practitioner. Specifically, one can easily find the definition of emulsion system in text books, for example, the book "Physical Pharmacy" by Alfred Martin, Williams & Wilkins (1993). The stability of emulsion is addresses on pages 490-494, a copy of these pages is attached hereto as Exhibit A. Therefore, Applicants believe that claim 1, as well as other claims are clear and defined to a person of ordinary skill. Accordingly, Applicants respectfully request the reconsideration and withdrawal of this ground of rejection.

Rejection of Claims under 35 U.S.C § 102(b)

The Examiner rejected claims 1,3 & 6-11 under 35 U.S.C. 102(b) as being anticipated by Hennik et al. (WO98/20093). The Examiner further stated that Hennik teaches a water-in-water emulsion of PEG and dextran mixed together which is taught to be useful to encapsulate a wide variety of pharmaceuticals. The reference anticipates the claim [sic] subject matter.

In response, Applicants respectfully traverse the above ground of rejection. Applicants maintain that the claimed invention is fundamentally different from Hennink. Hennink cannot anticipate the claimed invention.

Dextran and PEG are Immiscible. As described in several books, including reference 8 of the filed Information Disclosure Statement, See B. Z. Zaolavsky, Aqueous Two-phase partitioning; Marcel Dekker, New York, 1994, it is well known that solutions of dextran and PEG are immiscible. This aqueous two-phase system has been well used in the purification of

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proteins, since proteins can partition in the dextran phase preferentially, according to the same books.

This aqueous two-phase system disclosed by Hennink and others does not form a STABLE emulsion. As soon as stirring stops, two block phases are formed in this system. This characteristic prohibits the system being used for microencapsulation of pharmaceuticals. The concept for and experiments to prepare a stable aqueous-aqueous emulsion has yet been demonstrated.

Hennink's method teaches the way to stabilize the disperse phase of the aqueous two-phase system by solidifying it through a chemical CROSS-LINKING treatment. After cross-linking, the system will no longer be an emulsion but a suspension.

Applicants' claimed invention demonstrates a microencapsulation process for delicate agents free of cross-linking agents. The method is based on a stable aqueous-aqueous emulsion, not solidified suspension. The stable aqueous-aqueous emulsion is a technological breakthrough for protein microencapsulation that is based on introducing diffuse double layer to the system.

Hennink's method relies on chemical cross-linking. As a cursory, Applicants find the terms, "cross-linking, cross-linkable, or cross-linked" appeared 9 times in the abstract, 41 times in the main text, and 24 times in the claims of Hennink's patent (US 6,303,148, the U.S. version of WO98/20093, a copy of which the Examiner provided). Accordingly, Hennink cannot anticipate the Applicants' claimed invention.

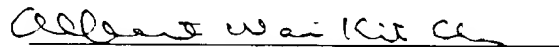
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To conclude, Applicants respectfully request that the above remarks be entered and made of record in the present application. An allowance is earnestly requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,



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